

 University College of the North <b>Policies &amp; Procedures Manual</b>	<b># Pages:</b> <b>13</b>	<b>Policy Number:</b> <b>AC-04-04</b>
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<b>Section:</b> <b>ACADEMIC – RESEARCH</b>	<b>Effective Date:</b> <b>November 20, 2017</b>	
<b>Title:</b> <b>ETHICAL CONDUCT OF RESEARCH INVOLVING HUMANS</b>	<b>Replaces:</b> <b>May 29, 2017</b>	

## 1. STATEMENT OF PURPOSE

This policy (hereinafter ‘Policy’) provides guidance to researchers employed by or under the auspices of UCN on the ethical conduct of research involving human participants in accordance with recognized protocols and nationally published principles.

## 2. PREAMBLE

The University College of the North (UCN) is established as a post-secondary institution under the University College of the North Act (2004). As defined in its mission statement, UCN’s purpose is “... to ensure Northern communities and people will have access to educational opportunities, knowledge and skills, while being inclusive and respectful of diverse Northern and Aboriginal values and beliefs.” The University College of the North is now in a position to engage in research and scholarly activities that honour the Knowledge of this land, and to work with all partners in respect and responsible research with the People and the Land of Northern Manitoba.

The **UCN Policy and Procedures Governing Ethical Conduct of Research Involving Humans** is based on the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) and is shaped by the Knowledge and Wisdom that has been shared by the People of this Land. The **UCN Policy and Procedures Governing Ethical Conduct of Research Involving Humans** outlines the principles and responsibilities UCN researchers and research partners must accept when conducting all research involving human participants. These principles require everyone who engages in research with the People of this Land, with those with whom we share this land, and with the Lands and the Waters, to demonstrate respect for the life here on the Land, and acknowledge the relationships that are enhanced by the research being conducted.

Research endeavours will be conducted in partnership with the communities involved, respecting the Traditional Knowledge that is held by the People of this Land, and provide service and information that respects all parties. Research partnerships will be built among community research committees and with other institutions.

## 3. CONSISTENCY WITH UCN MISSION AND ENDS

This Policy is consistent with and supports UCN's Mission and Ends:

*The Mission of the University College of the North is to ensure northern communities and people will have access to educational opportunities, knowledge and skills, while being inclusive and respectful of diverse Northern and Aboriginal values and beliefs.*

In pursuit of this mission and as set out in its Ends, University College of the North exists to encourage and facilitate:

1. *Knowledgeable, empowered people and communities.*
2. *Respect for Aboriginal cultures and identities and for diversity.*
3. *Research capacity developed for the north.*
4. *An educated populace for social and economic development of the north.*
5. *Accessible, equitable, affordable and relevant further education where people live.*

#### **4. RESEARCH TERMS**

Following are terms that researchers often encounter with research involving human participants.

##### **Aboriginal Peoples**

Aboriginal peoples include people of First Nations, Métis, and Inuit groups of Canada.<sup>1</sup>

##### **Autonomy and Consent**

Autonomy is the capacity to understand information and to be able to act on it voluntarily; the ability of individuals to use their own judgment to make decisions about their own actions, such as the decision to consent to participate in research. Research participants have to be sincerely informed of their role and nature of their participation including any foreseeable potential risks and/or benefits. Research Participants must willingly consent to participating and must be free to change their minds and withdraw from the research. Consent according to the TCPS2 is an indication of agreement by an individual to become a participant in a research project. The term "consent" means "free (also referred to as voluntary), informed and ongoing consent."<sup>2</sup>

##### **Burial Sites**

"Aboriginal burial grounds are the places where Aboriginal peoples buried their dead, often along with personal belongings intended to ensure their owners' safe passage into the spirit world."<sup>3</sup>

##### **Community engagement**

is a process that establishes interaction between a researcher or research team, and the community relevant to the research project. It signifies a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the research. The engagement may take many forms including review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The engagement may range from information sharing to active participation and collaboration, to empowerment and shared

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<sup>1</sup> As defined by the Constitution Act, 1982, s.35 (2)

<sup>2</sup> The Tri-Council Policy Statement 2 (2014)

<sup>3</sup> Peggy Blair, "The Non-Protection of Canadian Aboriginal Heritage (Burial Sites and Artifacts), Scow Institute (October 2005) <http://scow-archive.libraries.coop/library/documents/HeritageSitesFacts.pdf> Accessed June 12, 2015

leadership of the research project. Communities may also choose not to engage actively in a research project, but simply to acknowledge it and register no objection to it.<sup>4</sup>

### **Community customs and codes of research practice**

may be expressed in written or oral form. Consistent with the world views of particular First Nations, Inuit and Métis peoples, community customs and codes of research practice may embody kinship networks and responsibilities that include multi-generational obligations to ancestors and future generations. Ethical obligations often extend to respectful relations with plant, animal and marine life.<sup>5</sup>

### **Community**

describes a collectivity with shared identity or interests, that has the capacity to act or express itself as a collective. In this Policy, a community may include members from multiple cultural groups. A community may be territorial, organizational or a community of interest. “Territorial communities” have governing bodies exercising local or regional jurisdiction (e.g., members of a First Nations resident on reserve lands). “Organizational communities” have explicit mandates and formal leadership (e.g., a regional Inuit association or a friendship centre serving an urban Aboriginal community). In both territorial and organizational communities, membership is defined and the community has designated leaders. “Communities of interest” may be formed by individuals or organizations who come together for a common purpose or undertaking, such as a commitment to conserving a First Nations language. Communities of interest are informal communities whose boundaries and leadership may be fluid and less well-defined. They may exist temporarily or over the long term, within or outside of territorial or organizational communities.

An individual may belong to multiple communities, both Aboriginal and non-Aboriginal (e.g., as a member of a local Métis community, a graduate students’ society and a coalition in support of Aboriginal rights). An individual may acknowledge being of First Nations, Inuit or Métis descent but not identify with any particular community. How individuals define which of their community relationships are most relevant will likely depend on the nature of the research project being proposed.<sup>6</sup>

### **Non-Human Entities**

Non-human entities include animals and the environment. According to the Indigenous Peoples Council on Biocolonialism, environment can be defined as “the natural and cultural landscapes, including wildlife, flora, fauna, waters, and biogenetics.”<sup>7</sup>

### **Elders**

Within their communities, Elders are respected and honoured for their spirituality, wisdom, intelligence, life experience and teachings. Elders are also recognized for their love of the land, their language and for their knowledge of the traditions.

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<sup>4</sup> The Tri-Council Policy Statement 2 (2014)

<sup>5</sup> The Tri-Council Policy Statement 2 (2014)

<sup>6</sup> The Tri-Council Policy Statement 2 (2014)

<sup>7</sup> <http://www.ipcb.org/publications/policy/files/irpa.html> Accessed June 12,2015

## First Nations, Inuit and Métis Lands

include Indian reserves, Métis settlements, and lands governed under a self-government agreement or an Inuit or First Nations land claim agreement<sup>8</sup> or otherwise held pursuant to Aboriginal title, or treaty lands to which a First Nation has rights of access.<sup>9</sup>

## Human Research

Human research refers to any project that involves the collection of specimens, data or information from persons, through intervention or otherwise. Included are procedures that have a low degree of invasiveness (e.g. surveys, interviews, naturalistic observations, exercise or psychometric testing, examination of patient records), as well as more invasive procedures (e.g. blood sampling, insertion of a cannula, administration of a substance).<sup>10</sup>

## Human Subject/Participant

An individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as “human participant,” and in other policies/guidance as “subject” or “research subject.”<sup>8</sup> All research involving human participants must be brought before the REB for review and approval so as to ensure that research meets appropriate ethical standards and also protect research subjects/participants.

Research involving human participants shall be governed by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) (2014).

## Research

*Research* as defined in TCPS2 is defined as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.”

Any definition of *research* additionally and equally needs to be understood in a northern and Aboriginal context. For example, in Cree research can be defined as *nana'tonikewin*: “the art of looking or searching for something.” Appendix K of the Five Year Strategic Plan 2004-2009 titled ‘Bringing Together the Past, Present and Future: Building a System of Post-Secondary Education in Northern Manitoba’, notes that:

“As part of determining the structure for a Centre for Aboriginal Studies and Research (CASR) at UCN, consideration was given to building an understanding of “research” within the context of UCN, and out of this the various functions of the CASR. In the CASR Focus Group, it was noted that “research” needs to be understood in a northern and Aboriginal context. In Cree, research can be defined as *nanátonikewin*: “the art of looking or searching for something.” This was described as “needing to go back to the point where we got lost, then moving forward from there to restore balance.”

Appendix K also references that balanced research can be understood to be research that gives something back to students and communities in the form of participatory local and community based research initiatives. In other words, all participants, whether university or community based, should be seen as co-researchers all working to ensure that the conduct of research adheres to TCPS2’s core principles of Respect for Persons, Concern

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<sup>8</sup> The Tri-Council Policy Statement 2(2014)

<sup>9</sup> *Tsilhqot'in Nation v. British Columbia* <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/14246/index.do>

<sup>10</sup> From the University of Manitoba policy “The Ethics of Research Involving Humans” Accessed June 12, 2015

for Welfare – which in this context includes welfare of the collective, as understood by all parties involved – and Justice.

### **Indigenous peoples**

a term used in international or scholarly discourse; there is no consensus on the definition of the term “indigenous.” In some countries, other terms may be used. Self-identification is a fundamental criterion for defining Indigenous peoples.<sup>11</sup>

### **Indigenous knowledge – see Traditional Knowledge**

### **Inclusiveness**

Researchers shall not exclude prospective or actual research participants on the basis of such attributes as culture, language, religion, race, mental or physical disability, sexual orientation, ethnicity, linguistic proficiency, gender, or age, unless there is a valid reason for doing so.<sup>12</sup>

### **Intellectual Property Related to Research**

Intellectual property is defined in an academic context as any production of research, scholarly or other creative activity, including curriculum development and institutional programming which is the result of research. Intellectual property applies to all original scholarly, scientific, literary, dramatic, musical, and artistic works and to recorded works as defined in the University College of the North’s Collective Agreement. In collaborative research, intellectual property rights should be discussed by researchers, communities and institutions. The assignment of rights, or the grant of licences and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.<sup>13</sup>

### **Research Ethics Protocol**

A research ethics protocol is a document submitted by the applicant for consideration by the REB. This document contains a detailed description of the rationale/purpose of the study, procedures to be followed in soliciting participants for the research, obtaining their informed consent when possible, collecting their information or data, protecting their privacy or anonymity, and providing feedback regarding the study at its conclusion.<sup>14</sup>

### **Traditional knowledge**

the knowledge held by First Nations, Inuit and Métis peoples, the Aboriginal peoples of Canada. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is determined by an Aboriginal community’s land, environment, region, culture and language. Traditional knowledge is usually described by Aboriginal peoples as holistic, involving body, mind, feelings and spirit.

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<sup>11</sup> Tri-Council Policy Statement 2 (2014)

<sup>12</sup> Tri-Council Policy Statement 2 (2014)

<sup>13</sup> Tri-Council Policy Statement 2 (2014)

<sup>14</sup> Tri-Council Policy Statement 2 (2014)

Knowledge may be expressed in symbols, arts, ceremonial and everyday practices, narratives and, especially, in relationships. The word tradition is not necessarily synonymous with old. Traditional knowledge is held collectively by all members of a community, although some members may have particular responsibility for its transmission. It includes preserved knowledge created by, and received from, past generations and innovations and new knowledge transmitted to subsequent generations. In international or scholarly discourse, the terms *traditional knowledge* and *Indigenous knowledge* are sometimes used interchangeably.<sup>15</sup>

## 5. GENERAL PRINCIPLES GUIDING THIS POLICY

1. This Policy shall be guided in all its aspects by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*, the primary accepted authority in Canada governing research with human participants.
2. The purpose of ethics review when undertaking research with humans is to foster and ensure research/scholarly practices that respect the rights and dignity of research participants, promote the integrity of researchers/scholars, and uphold the principle of academic freedom.
3. While approval of the ethics of research is the ultimate responsibility of the University College of the North's Research Ethics Board (REB), the emphasis in review should be on collegial practices and educational initiatives, in an atmosphere of respect for both ethical rigour and academic inquiry.
4. Any research/study or inquiry into individual and collective Aboriginal knowledge(s), cultures, histories, arts, spiritualities, and practices which involve partnerships in research, shall be reviewed and approved by the Aboriginal communities and peoples involved.
5. Researchers must accept a degree of community input and control of the research process. They are obligated "to give something back" to the Aboriginal and northern community. Researchers must acknowledge the cooperation and contribution(s) of Aboriginal co-researchers, including co-authorship. Financial remuneration resulting from joint/collaborative research should be fairly shared amongst authors and/or others holding copyright.
6. Adoption and implementation of this Policy shall not circumscribe the Article on Academic Freedom of the University College of the North's Collective Agreement. Notwithstanding that all proposals involving humans shall require review under this Policy, the REB shall not have, or presume to have, the power to recommend disciplinary action, to impose sanctions or to cause discipline to be imposed on members of the MGEU Bargaining Unit.

## 6. EXCEPTIONS TO ETHICS REVIEW

Certain activities involving human participants proposed for a research study may not require ethics review. Because many variables (e.g. legislative requirements around privacy; digital technologies; etc.) may be involved and/or in a process of transition, researchers are required to consult TCPS2 for the most current guidance in determining whether or not their research may be exempt from ethics review.

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<sup>15</sup> Tri-Council Policy Statement 2 (2014)

## 7. ETHICS REVIEW OF RESEARCH PROJECTS LED BY OTHER INSTITUTIONS IN WHICH UCN RESEARCHERS ARE PARTICIPATING AS ACADEMIC COLLABORATORS

For projects involving human participants in northern Manitoba being led by a principal investigator at another institution in which UCN researchers are collaborators, such projects must come to UCN's REB for at the same time as they are undergoing ethics review at the principal investigator's institution. The rationale for this is to ensure the ethics of the project are additionally reviewed specific to northern and Aboriginal cultures and ways of knowing.

## 8. ETHICS REVIEW OF RESEARCH BY INVESTIGATORS EXTERNAL TO UCN THAT INVOLVES UCN PARTICIPANTS

Researchers from institutions external to, and who have no affiliation with, UCN may wish to involve UCN faculty, non-teaching staff or students in their research studies. They may have already obtained ethics approval from their home institution before approaching UCN. Regardless of such approval, external investigators wishing to involve UCN personnel or students are required to disclose their project to UCN's REB as the first step in determining whether or not formal ethics review by UCN's REB will be required.

## 9. ETHICS REVIEW OF PROGRAM EVALUATION AND QUALITY ASSURANCE ACTIVITIES

REB review would be required only if program evaluation or similarly-purposed activity falls within the TCPS2 definition of research or serves as a component of a research project. Although program evaluation may share some methods and techniques with those employed in research (such as data collection and data analysis), the intent and objectives of the data collection, as well as the further use of the collected data, may be determining factors for establishing whether it is research and whether it should be reviewed by an REB. Whether or not information from the study will be published is not in and of itself a determinant of the need for ethics review. The determination of whether a program evaluation/quality assurance study is research and therefore requires REB review should be made on a case-by-case basis, and should be guided by the definition of research in TCPS2.

TCPS2 exempts from REB review program evaluation activities normally administered in the ordinary course of operation of an organization. If, however, the collected data for such activities is later proposed for research purposes, it is considered secondary use of information not originally intended for research, and may require REB review at that time. Where in doubt about the applicability of TCPS 2 or the requirement for REB review of a particular research project, the researcher/investigator should consult the REB.

## 10. RESPONSIBILITIES OF RESEARCHERS UNDER THIS POLICY

The term 'researchers' under this Policy encompasses any and all individuals under UCN auspices intending to involve human participants in their research. This can include but not be limited to faculty, non-instructional staff, Elders, post-doctoral scholars, students and others. This Policy follows the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)*. The core principles underlying TCPS2 are **Respect for Persons**, **Concern for Welfare**, and **Justice**. These principles are complementary and interdependent. How they apply and the weight accorded to each during ethics review will depend on the nature and context of the research being undertaken.

**All researchers must take into account, and address, respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, respect for cultural traditions and practices, balancing of harms and benefits, minimizing harm, and maximizing benefit. This will involve identifying levels of risk, and may involve peer review of the project's science/scholarship when the risk is more than minimal.**

Further to respect for privacy and confidentiality, in addition to the principles and guidelines in this Policy, researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements. Researchers may face situations where they experience a tension between the requirements of the law and the guidance of the ethical principles in this Policy. In such situations, researchers should strive to comply with the law in the application of ethical principles.

Because each research project is unique, this Policy cannot and does not set out to be an exhaustive guide covering all situations and eventualities. Therefore, under this Policy researchers are responsible for:

- Developing and maintaining a strong and current working knowledge of TCPS2 in its entirety, and
- In all instances, closely consulting TCPS2 for guidance on specifics pertaining directly to their research, and designing and conducting their research accordingly. This is to also include consulting additional resources (such as *TCPS2 Interpretations*) as these are added and updated on the TCPS2 website.

In addition, and more specifically, those engaged in research and scholarly activity at or under the auspices of UCN are required:

1. To consider and to resolve satisfactorily any ethical issues raised by the project they plan to undertake, including consulting with members of the REB.
2. Not to undertake any project involving living human participants that requires review without obtaining the necessary approval. In addition, research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells shall not be undertaken without review and approval. This applies to materials derived from living and also deceased individuals.
3. To submit their research proposals, including proposals for pilot studies, for REB review and approval of ethical acceptability before beginning recruitment of participants, accessing data, or collecting human biological materials. REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.
4. To disclose in their applications any real or apparent conflicts of interest regarding their relationship with potential research participants or regarding the potential use of the research findings.
5. To report to the University College of the North's Research Ethics Board any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare. In particular, this would include adverse participant responses to the research that exceeds the level of response anticipated and provided for in their approved proposal.
6. Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.



## 11. RESPONSIBILITIES OF UCN RESEARCH ETHICS BOARD UNDER THIS POLICY

UCN's Research Ethics Board shall be guided by TCPS2 in all its deliberations and actions. **Review must take into account, and address, respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, respect for cultural traditions and practices, balancing of harms and benefits, minimizing harm, and maximizing benefit. This will involve identifying levels of risk, and may involve peer review of the project's science/scholarship when the risk is more than minimal.**

Because each ethics application is unique, this Policy cannot and does not set out to be an exhaustive guide covering all situations and eventualities that may occur during ethics review. Therefore, under this Policy REB members are responsible for developing a knowledgeable and adaptive approach to ethics review through:

- Developing and maintaining a strong and current working knowledge of TCPS2 in its entirety, and
- Actively consulting TCPS2 for guidance as part of the process of reviewing all ethics applications submitted by researchers. This is also to include consulting additional resources (such as *TCPS2 Interpretations*) as these are added and updated on the TCPS2 website

## 12. PROCEDURES FOR SUBMISSION AND REVIEW OF ETHICS APPLICATIONS

**NOTE: THE FOLLOWING PROCEDURES APPLY TO BEHAVIOURAL/NON-MEDICAL RESEARCH ONLY. FOR PROCEDURAL INFORMATION RELATING TO MEDICAL/CLINICAL RESEARCH, CONTACT THE UCN REB COORDINATOR.**

### PART A: SUBMISSION OF ETHICS APPLICATIONS

#### 1. FACULTY/INVESTIGATOR-INITIATED RESEARCH

- a. Researcher consults TCPS2 for guidance on identifying and addressing the ethical dimensions and risks of their proposed research/scholarly activity.
- b. Researcher completes UCN research ethics Application and Letter of Consent forms. The most current versions are to be accessed from the UCN website <https://www.ucn.ca/sites/research/REB/Pages/Research-Ethics-Board.aspx> or by contacting the UCN Research Ethics Board Coordinator
- c. Researcher submits signed and dated Application and Letter of Consent forms, plus any required supporting documents, in PDF form only to the UCN Research Ethics Board Coordinator

#### 2. STUDENT-INITIATED RESEARCH

- a. Student researchers must first secure the supervision of a faculty member for any research they propose to undertake.
- b. Student researcher consults TCPS2 for guidance on identifying and addressing the ethical dimensions and risks of their proposed research/scholarly activity.
- c. Student researcher completes UCN research ethics Application and Letter of Consent forms. The most current versions are to be accessed from the UCN website <https://www.ucn.ca/sites/research/REB/Pages/Research-Ethics-Board.aspx> or by contacting the UCN REB Coordinator.

- d. Student researcher submits signed and dated Application and Letter of Consent forms, plus any required supporting documents, in PDF form only to the UCN REB Coordinator. Applications must indicate the faculty supervisor for their project and also include that person's signature.

### **3. COURSE-BASED RESEARCH**

As part of their teaching strategies relative to research skills development, many instructors assign class projects and activities in which students are to collect data from human participants. These projects may be carried out by individual students, small groups, or as a single class project. Course-based research assignments vary in scope, but may include:

- Conduct interviews, administer standard tests, or distribute questionnaires to develop interview or questionnaire design skills;
- Conduct small research projects where students pose research questions, gather data from human participants, and analyse the data for presentation; or
- Engage in other activities that would be considered research within the disciplinary traditions in which the course is being taught.

Course-based research projects and activities vary widely in scope and may not fit the conventional framework of research, in that the results are not intended for publication or generalization to other situations. In addition, course-based research projects are typically those that meet the definition of 'minimal risk' to participants as defined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) as follows:

“For the purposes of this Policy, “minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”

Nonetheless, the fact that some potential for risk does exist, requires that the protocols and consent processes of course-based research be reviewed by the Research Ethics Board.

### **PROCEDURES FOR COURSE-BASED RESEARCH**

#### **General**

For course-based projects that meet the TCPS 2 definition of minimal risk research, students will not be required to submit individual ethics application for REB review. The faculty member responsible for the course would complete an Application together with Letter of Information/Consent that covers the entire class. If granted, the course-based REB approval will be for a year and is subject to yearly renewal upon receipt of application from the faculty.

#### **Course Projects Repeated across Sections and/or Semesters**

Course-based research assignments that are repeated across sections and/or semesters will be submitted as a regular research protocol. Once a protocol has been approved for a particular course number, it can be applied to different sections, or years (however not crossing from undergraduate to graduate or vice

versa). Annual renewals are not required; however, re-approval, through a new submission to the REB, is necessary after five years.

Any faculty member who is unsure if a class project falls within the parameters of course-based research outlined in this document may contact the UCN REB Chair or REB Coordinator.

## **PART B: REVIEW OF ETHICS APPLICATIONS**

### ***Initial Review***

1. The REB shall select the level of REB review based on the level of foreseeable risks to participants guided by a proportionate approach to review, i.e. the lower the level of risk, the lower the level of scrutiny, and the higher the level of risk, the higher the level of scrutiny.

Two levels of research ethics review may apply:

- 1) Full REB review – research ethics review by the full REB is normally the default requirement for research involving humans
  - 2) Delegated REB review of minimal risk research – the REB may delegate research ethics review to an individual or individuals. Delegates shall be selected from among the REB membership with the exception of the ethics review of student course-based research. Where it is determined that the research is of minimal risk, the REB may authorize a delegated research ethics review in accordance with TCPS2.
2. The REB will provide written notification of its decision to the researcher. All decisions shall be recorded in formal meeting minutes that are retained in a locked filing cabinet in the Research Officer's office.

### ***Continuing Review***

As with initial review, the REB shall select the level of continuing review based on the level of foreseeable risks to participants based on the proportionate approach to review, i.e. the lower the level of risk, the lower the level of scrutiny, and the higher the level of risk, the higher the level of scrutiny. The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with this proportionate approach. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).

## **PART C: RENEWAL OR AMENDMENT OF ETHICS APPLICATIONS**

Researchers are required to request approval from the REB to continue involving human participants in their study beyond one year from the original protocol approval date; or to make amendments to the original approved protocol.

In both instances, the researcher shall complete the 'Request for Research Ethics Renewal / Amendment Form' for submission to the REB Coordinator. The Coordinator shall document receipt of the request, and forward it to the Chair. The Chair shall do the initial review. Authority is given to the Chair to determine, based on TCPS 2, to determine the level of risk to participants. Should the Chair determine the level to be minimal, the Chair has sole authority to approve the request. Should the Chair

determine the level of risk to exceed minimal, the Chair shall bring the request to the full board for review and decision.

All Renewal or Amendment requests received, and decisions made, shall be documented in the minutes of the next REB meeting following receipt of the request.

### **13. REVIEW OF MULTI-JURISDICTIONAL RESEARCH**

Due to the complexity of reviewing the ethics of research being undertaken by more than one institution and/or multiple review by research ethics boards, together with the unique nature of each research project, the UCN REB shall consult TCPS2 for guidance on a case-by-case basis.

### **14. RECONSIDERATION AND APPEAL OF REB DECISIONS**

Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project. The onus is on researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by TCPS2.

In cases where researchers and REBs cannot reach agreement through reconsideration, researchers may proceed to appeal. The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before the researcher initiates an appeal. An appeal can be launched for procedural or substantive reasons.

An appeal committee shall be established per guidance provided in TCPS2, with the authority to review negative decisions made by an REB. In so doing, the appeal committee may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final, and shall be communicated in writing (in print or by electronic means) to researchers and to the REB whose decision was appealed.

Decisions respecting either reconsideration or appeal may not be appealed to the UCN Learning Council or its Executive Committee.

### **15. RESEARCH INVOLVING ABORIGINAL AND NORTHERN PEOPLES: ADDITIONAL RESOURCES FOR REVIEW**

In addition to consulting this policy, those conducting research and scholarly activity involving Aboriginal and northern peoples will consult the following:

Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North*, 2003. <http://acuns.ca/website/ethical-principles/>

First Nations Principles of OCAP (ownership, control, access and possession)  
<http://fnigc.ca/ocap.html>

[United Nations Declaration on the Rights of Indigenous Peoples](http://undesadspd.org/indigenouspeoples/declarationontherightsofindigenouspeoples.aspx)  
<http://undesadspd.org/indigenouspeoples/declarationontherightsofindigenouspeoples.aspx>

[Indigenous Bar Association, \*Understanding and Implementing the UN Declaration on the Rights of Indigenous Peoples\*](http://www.indigenousbar.ca/pdf/undrip_handbook.pdf)

[http://www.indigenousbar.ca/pdf/undrip\\_handbook.pdf](http://www.indigenousbar.ca/pdf/undrip_handbook.pdf)

## **16. REVIEW OF POLICY AND PROCEDURES**

This policy and supporting documents are to be reviewed and updated at the last meeting of every academic year, with the aim of addressing changes and new developments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)* and within any research or research centres taking place within UCN, as well as in response to changes within the broader research environment provincially, nationally and internationally.

### **RELATED POLICIES AND GUIDELINES**

AC-04-02 Integrity in Research and Scholarly Activity

AC-04-03 Conflict of Interest in Research and Scholarly Activity

CA-01-01 Protocol Regarding Elders and Traditional People and Activities

CA-01-02 Smudging Policy